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May 28, 1999

VIA TELEFAX AND
FEDERAL EXPRESS

Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Attn: Brian Pendleton

Re: Comments to FDA Proposed Memorandum of Understanding
Docket No.: 98N-1265
Our File No.: 22-781WO-001FD

Dear Mr. Pendleton:

I am writing to request that you extend the comment period for the Food & Drug Administration's ("FDA") January 21, 1999 notice and issuance of the proposed Federal/State Memorandum of Understanding on interstate distribution of compounded drug product (the "proposed MOU") until August 1, 1999.

The comment period should be extended to allow state Boards of Pharmacy to review and provide comment to the FDA. The MOU was discussed at the National Association of Boards of Pharmacy ("NABP") annual meeting on May 24, 1999. An extension is necessary to allow sufficient time for the Boards to consider the FDA's presentation. Additional time is also warranted as NABP was not able to fully discuss the draft MOU with its members until the May meeting. This would be consistent with the statute which requires the FDA to draft the MOU in consultation with NABP. Keeping the comment period open until August 1, 1999 would allow State Boards of Pharmacy adequate time following the meeting to discuss the MOU and submit meaningful comments to your office.

98N-1265

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HOLLEB & COFF
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Dockets Management Branch (HFA-305)

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If you have any questions regarding these comments, feel free to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Matthew J. Murer", with a stylized flourish extending to the right.

Matthew J. Murer

MJM/klb

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City **CHICAGO** State **IL** ZIP **60603**

2 Your Internal Billing Reference Information **22-781WD-001FD**

3 To Recipient's Name **Brian Pendleton** Phone ()

Company **Dockets Management Branch (HFA-305)**
Food & Drug Administration

Address **5630 Fishers Lane, Room 1061**

City **Rockville** State **MD** ZIP **20852**

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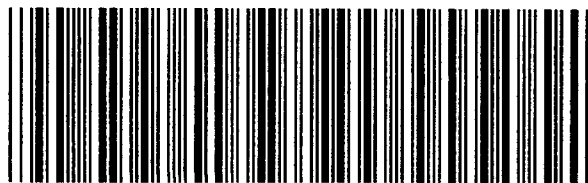
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